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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,871	06/04/1998	RUDOLF CAROLUS MARIA BARENDSE	97253-A	3289

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EXAMINER

RAMIREZ, DELIA M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/089,871

Applicant(s)

BARENDSE ET AL.

Examiner

Delia M. Ramirez

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,19,21-28 and 31-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,19,21-28 and 31-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1652

DETAILED ACTION

Status of the Application

Claims 18-19, 21-28, 31-35 are pending.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/20/2005 has been entered.

Applicant's amendment of claims 18-19, 21-28, 32-35 and cancellation of claims 20, 39-40 in a communication filed on 10/20/2005 are acknowledged. As indicated by Applicant in the response to the Final Action of 2/22/2005, support for the amendments made to the claims is found in page 8, lines 26-28.

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 18-19, 21, 24-28, and 31-35 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996).
3. Claims 22-23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) as applied to claims 18-19, 21, 24-28, and 31-35 above, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978).

Art Unit: 1652

4. These rejections have been discussed at length in Paper No. 30, mailed on 2/24/2003, Paper No. 33, mailed on 11/3/2203, the Advisory Action mailed on 6/3/2004, and the Final Action mailed on 2/22/2005.

5. Claims 18 and 31-35 have been amended such that they now require specific mechanical processes for the preparation of the granulate. One of the processes recited is high shear granulation. Claims 19 and 22-28 require a divalent cation in the granulate. The claimed invention is deemed obvious over the teachings of Nielsen et al., Ghani, and Markussen et al. for the following reasons. Ghani teaches mechanical methods for preparation of the granulate such as high shear granulation (column 3, lines 66-67). It would have been obvious to one of ordinary skill in the art to prepare the granulate using the different mechanical processes recited in the claim, including high shear granulation. A person of skill in the art would be motivated to use these methods since they are commonly used processes in the industrial manufacture of granules. One of skill in the art has a reasonable expectation of success at using these methods since they are commonly used in the industrial preparation of granules. With regard to claim 19 and dependent claims 22-28, it is noted that the addition of divalent cations, such as Zn, to the granulate would be obvious to one of skill in the art at the time the invention was made in view of the teachings of Ghani and what is known in the art. Ghani teaches that other ingredients can be added to enzyme granulates such as metallic salts (column 3, lines 14-25). A person of skill in the art would be motivated to add, for example, Zn (divalent cation) salts as it is well known in the art that Zn is an essential mineral found in many nutritional supplements. One of ordinary skill in the art has a reasonable expectation of success at adding Zn to the enzyme granulate as this mineral is widely used to enhance the nutritional value of a great number of foods. Therefore, the teachings of Nielsen et al., Ghani and Markussen et al. as previously discussed render the claimed invention obvious over the prior art.

Art Unit: 1652

6. Claims 39 and 40 were rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and Markussen et al. (U.S. Patent No. 4106991, 1978) as applied to claims 22-23 above, and further in view of Haarasilta (GB 2-139868A, 1984). In view of the cancellation of claims 39-40, this rejection is hereby withdrawn.

7. Claims 18-19, 21-22, 24-28, and 31-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996), and further in view of Haarasilta (GB 2-139868A, 1984). This rejection is necessitated by amendment.

Nielsen et al. teaches an *Aspergillus* phytase-containing granulate comprising 10,000 FTU/gram of total composition (page 5, lines 25-29; page 10, lines 16-21; page 11, lines 27-30; page 12, lines 18-21). Nielsen et al. teaches that the phytase is derived from several strains of *Aspergillus* such as *niger* and *ficum* (page 7, lines 4-6). Furthermore, Nielsen et al. teaches a phytase-containing feed additive comprising additional glucosidase enzymes such as xylan-endo-1,3- β -xylosidase and endo-1,6- β -glucanase (page 11, lines 5-19). Nielsen et al. teaches that the phytase granulate can be used as an additive for animal feed (page 10, lines 16-21). Nielsen et al. does not teach the specific mechanical methods for granule manufacture recited or a phytase-containing granulate comprising a divalent cation, an edible carbohydrate polymer, starch, a gel-forming compound, or an edible oil.

Ghani teaches an enzyme granulate and compositions thereof, wherein a solid carrier can be a starch-containing compound such as soy flour, soy grits, corn flour, ground corn cobs, etc. (column 2, lines 25-34). In one of the examples provided by Ghani, the carrier contains 90% (w/w) of soy flour (column 6, lines 43-48; 10 g corn syrup solids per 100 g soy flour). Ghani also teaches enzyme granulates which comprise hydrolyzed starches and gums (column 2, lines 35-52) as well as low viscosity

Art Unit: 1652

algins and algin blends (column 2, lines 53-57; gel forming compounds). In addition, Ghani teaches that the amount of enzyme to be used in a granule can be adjusted according to the activity desired for the finished product (column 3, lines 45-47). Ghani teaches mechanical methods for preparation of the granulate such as high shear granulation (column 3, lines 66-67). Ghani does not teach an enzyme granulate where the enzyme is a phytase.

Haarasilta teaches a fodder in granulated form which comprises soy oil (page 2, lines 13-15) and teaches that to aid in the formation of stable granules, inorganic salts can be added which contain divalent cations such as Ca or alkaline earth metal cations (page 2, lines 19-21). Haarasilta also teach extrusion as a method to produce the granules (page 1, lines 42-46). Haarasilta does not teach a phytase granulate.

Claims 18 and 31-35 are drawn in part to a phytase granulate having at least 6000 FTU per gram where the granulate is prepared by extrusion or high shear granulation, wherein the granulate is obtained from a solution having a concentration of at least 14000 FTU per gram of solution, and wherein the granulate is prepared using a non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer. Claim 19 is directed to a phytase granulate having at least 6000 FTU per gram, wherein the granulate is obtained from a solution having a concentration of at least 14000 FTU per gram of solution, wherein the granulate is prepared using a non-fibrous solid carrier comprising at least 15% (w/w) of an edible carbohydrate polymer, and wherein the granulate contains at least one divalent cation. Claim 21 is directed in part to the granulate of claim 19 wherein the granulate comprises a gel-forming compound. Claims 21-22 are directed in part to the granulate of claim 19 wherein the granulate contains an edible oil. Claim 24 is directed to the granulate of claim 19 wherein the granulate additionally comprises an endo-xylanase and/or a β -glucanase, whereas claim 25 adds the limitation that the granulate additionally comprises starch. Claim 26 adds the limitation that the phytase is not heat tolerant and claims 27-28 add the limitations that the phytase is derived from fungus or derived from *Aspergillus*.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an *Aspergillus* phytase granulate having at least 6000 FTU per gram which can be used as additive in animal feed, as taught by Nielsen et al., using a solid carrier which comprises at least 15% of an edible carbohydrate polymer, as taught by Ghani and further adding (1) an endo-xylanase and/or β -glucanase as taught by Nielsen et al, (2) a compound which would provide at least one divalent cation as taught by Haarasilta, (3) an edible oil taught by Haarasilta, or (4) a gel-forming compound as taught by Ghani, wherein the granulate is made by extrusion, as taught by Haarasilta or by high shear granulation, as taught by Ghani. A person of ordinary skill in the art is motivated to (1) make a phytase-containing granulate which contains an edible carbohydrate and/or a divalent cation for the benefit of adding nutritional value to the granulate and also due to the fact that phytases aid in the digestion of phytate-containing substances, (2) use extrusion or high shear granulation as they are commonly used in industry for granulate manufacture, (3) add a gel-forming compound for the benefit of solidifying the granules and maintaining moisture and softness, (4) add an edible oil to the phytase granulate to facilitate binding of hydrophobic compounds which may be part of the granulate, to add nutritional value to the granulate, or as a lubricant to avoid adhesion in the granulator or the extruder, and (5) add an endo-xylanase and/or β -glucanase since these are proteolytic enzymes which would help in the digestion of complex carbohydrates which might be present in the feed. One of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate by extrusion or high shear granulation wherein the granulate comprises edible carbohydrates, gel-forming compounds, starch, and endo-xylanase/ β -glucanase, since Ghani teaches the use of high shear granulation and enzyme granules which are made with solid carriers containing edible carbohydrates such as soy flour, soy grits, corn flour, ground corn cobs, corn syrup, etc. and contain gel-forming compounds, Nielsen et al. teach phytase granules comprising endo-xylanase/ β -glucanase, and Haarasilta teaches the use of extrusion for granulate manufacture. Furthermore, one of ordinary skill in the art has a reasonable expectation of success at

Art Unit: 1652

making the phytase-containing granulate further comprising an edible oil and a divalent cation since Haarasilta teaches fodder granules which contain soy oil and Ca cations. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nielsen et al. (WO 95/28850, November 2, 1995) in view of Ghani (U.S. Patent No. 6120811, filed 10/4/1996) and Haarasilta (GB 2-139868A, 1984) as applied to claim 22, and further in view of Markussen et al. (U.S. Patent No. 4106991, 1978). The teachings of Nielsen et al., Ghani and Haarasilta have been discussed above. Neither Nielsen et al., Ghani or Haarasilta teach the phytase granulate comprising derivatized cellulose. Markussen et al. teach enzyme granules which contain polyvinyl alcohol (PVA) and/or cellulose derivatives such as carboxy-methyl cellulose (CMC; column 3, lines 9-18). Markussen et al. does not teach phytase-containing granulates.

Claim 23 is drawn in part to the phytase-containing granulate of claim 19, as described above, further comprising CMC.

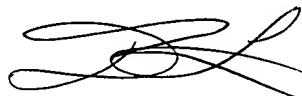
It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the *Aspergillus* phytase granulate of Nielsen et al., Ghani and Haarasilta as described above, further comprising CMC as taught by Markussen et al. A person of ordinary skill in the art is motivated to add CMC to the phytase granulate since this is a commonly used binder in the manufacture of granulates. One of ordinary skill in the art has a reasonable expectation of success at making the phytase-containing granulate further comprising CMC since Markussen et al. teach enzyme granules which contain these compounds. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

Art Unit: 1652

Conclusion

9. No claim is in condition for allowance.
10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.



Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
January 6, 2006